

REMARKS

Claims 1-42 remain in this application, of which Claims 4-12, 15, 17 and 21-32 have been withdrawn from examination as being directed to non-elected species. Several typographical errors noted in the specification have been corrected.

Of the claims under consideration, Claims 1, 2, 13, 18-20 and 33 are independent.

Claims 1-3 and 20 were rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent 5,728,157 (Prescott), and Claims 13, 14, 16 and 18, as being anticipated by a portion of the Synthes catalog cited by Applicant (Synthes). Claims 19, 33-37 and 39-42<sup>1</sup> were rejected under 35 U.S.C. § 103(a) as being obvious from *Prescott '157*, and Claim 38, as being obvious from that patent in view of U.S. Patent 5,061,280 (Prescott).

After a careful study of the prior art and the rejections set out in the Office Action, it is found impossible to agree with those rejections, for at least the following reasons.

The present invention, as is discussed in detail in the present application, relates to surgical kits, and to components (implants) for such kits. Of particular concern are components and kits for use in cosmetic or reconstructive procedures. It would be advantageous to have such implants that can easily and reliably be secured to each other, and also to facilitate the surgeon's task by providing kits of pre-assembled combinations of augments with the structures that will secure them in place. One important aspect of the present invention is the provision of a simple and yet effective structure for a surgical implant in which two pieces can be quickly secured to each other by the surgeon as needed. One of the two pieces is provided with a female connector, and the other with a male connector, the male and female connectors being structured such that they can be made to engage each other, and be attached to each other, snappingly. That is, the two connectors

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<sup>1/</sup> From paragraphs 17 - 20 of the Office Action, it is understood that this rejection is intended to apply to Claims 39-42 as well.

engage each other in the same fashion as do the two parts of a snap such as one finds on blue jeans and other articles of apparel (as is discussed in the application at pages 27 and 28, the male and female elements may depart from the exact shapes commonly seen in apparel; a number of contemplated variations within the scope of the invention are set out in the indicated passage).

In particular, Claim 1 is directed to a surgical implant having a connector element. That connector element includes an element selected from the group consisting of (1) a female connector element and (2) a male connector element, those male and female connector elements being respectively shaped such as to be snappingly attachable to each other. As will be clearly understood from a review of the present application, the term “snappingly attachable”, while it does encompass the manner of engagement described above, does not include every type of engagement in which friction occurs, or in which some deformation of one or both elements occurs.

At the very least, Applicant cannot agree that anything in the prior art even hints at the recited snapping fit.

*Prescott '157* relates to a number of biocompatible composite prostheses, made of an elastomeric matrix having hydroxylapatite particles dispersed therein, the particles making up 25 - 70% by weight of the prosthesis. After curing of the matrix, the resulting matrix is flexible, such as to permit distortion from its original shape. Upon removal of the distorting force, however, the prosthesis will return to its original shape.

The Examiner cites Fig. 6 of *Prescott '157* as showing a structure that he deems to anticipate Claim 1 (among other claims). That Fig. shows what is described in *Prescott '157* as being “an exploded perspective view of a nasal prosthesis in accordance with the present invention” (col. 4, lines 15 and 16), and “an exploded perspective view of a set of disks 40 and 42 having a shape useful to close nasal perforations” (col. 6, lines 42 and 43). No other disclosure concerning Fig. 6, or explaining the nature or characteristics of what is shown in that Fig., has been found in *Prescott '157*. In particular, no disclosure

has been found, or pointed out by the Examiner, in *Prescott '157* to the effect that the characteristics of the nasal prosthesis shown in Fig. 6 would even permit a snapping fit to be formed. Disk 40 has a roughly central stud, and a roughly central hole is shown in disk 42. To begin with, however, it is not even clear from *Prescott '157* that the hole in disk 42, shown on the near side, is also present on the other side of that disk. (Since there is no statement in *Prescott '157* that the stud is to be inserted into any hole, it is apparent that if in fact there is no hole on the side facing the stud, there is no basis at all for assuming that insertion was contemplated; the patent does not say that insertion is intended, and does not say or otherwise communicate that a hole is provided facing the stud, or of the right size for the stud.)

What is even more important, however, is the complete absence of any suggestion that the stud (or any other portion of what is shown in Fig. 6) has a shape that would make a snapping fit possible. Applicant agrees that a reference may fairly be cited for all that it teaches; what is *not* permissible is to cite a reference for a feature that is not *clearly and indisputably* present in the reference. The only exception is if the presence of the feature in question is somehow implicit, or completely inherent, that is, if the presence of the feature *necessarily must* follow as an inescapable consequence of that which is clearly disclosed by the reference. MPEP §§ 706.02,<sup>2</sup> 2112. There is in fact no statement or other disclosure that has either been found or been pointed out in *Prescott '157* to the effect that the dimensions and shape of the stud and the hole shown in Fig. 6 are (1) even such as to permit the stud to be inserted into the hole at all, and in addition (2) such as to cause interference of the two pieces if the stud is so inserted.

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<sup>2/</sup> "In other words, for anticipation under 35 U.S.C. 102, the reference must teach *every* aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. [emphasis added]" MPEP § 706.02.

Even assuming that such disclosure were present (and it is not), there would in addition need to be clear disclosure that upon such insertion being effected, the result would be a snapping fit, as recited in Claim 1, and not just a friction fit.

Applicant submits that it is inescapable that the rejection of Claim 1 over *Prescott '157* is based on the impermissible reading into that reference of features that are not actually disclosed. It is believed plain that Claim 1 is not remotely anticipated by *Prescott '157*.

Moreover, there is no question of obviousness:

“[I]n a rejection based on 35 U.S.C. 103, the reference teachings must somehow be modified in order to meet the claims. The modification must be one which would have been obvious to one of ordinary skill in the art at the time the invention was made. [emphasis added]” MPEP § 706.02.

It is of course not proper to modify a reference to meet the language of a claim for the purpose of making a rejection, where the proposed modification of the reference is one for which a person of merely ordinary skill in the relevant art would have had no motivation, or would have lacked a reasonable expectation of success. MPEP § 2143. While Applicant notes that snapping fits, *per se*, have been known for generations (for example, on jeans and other articles of clothing), there is nothing in the record that provides even a hint of motivation for a person in the art of medical implants to try to use such a technique in the design of a medical implant. There is therefore no basis on which one could conclude that it would somehow have been obvious to adopt such a fitting in the relevant field.

For these reasons, Applicant strongly urges that Claim 1 is plainly allowable over *Prescott '157*.

Independent Claims 2 and 20 are believed to be clearly allowable over *Prescott '157* for at least the same reasons as is Claim 1.

Independent Claim 13 is directed to a strut that has at least one connector element. The connector element includes an element selected from the group consisting of (1) a female connector element and (2) a male connector element, the male and female

connector elements being respectively shaped such as to be snappingly attachable to each other.

*Synthes*, cited by the Examiner against this claim, shows at page 1-40 (cited specifically in the Office Action) a cruciform screwdriver blade, various drill bits with a Stryker J-latch, various maxillary L-plates, and a number of sizes and shapes of titanium screws. Although the Office Action does not make completely clear which structure is relied upon as anticipating Claim 13, it is assumed that the intention is to rely on the L-plates, which as shown have apertures through which they can be screwed in place to a bone, such as by means of screws like those shown on the same page. It is also surmised that those screws are intended as the male connector.<sup>3</sup>

First, it is noted that a threaded screw does not form a snapping engagement with an aperture, but a threaded engagement. If too large a screw is used (apparently the intended suggestion in the Office Action), the result is still not a snapping engagement, but a permanent deformation of the aperture in the L-plate. Aside from the unacceptability of such damage to the L-plate, the screw could apparently be withdrawn through the deformed aperture as easily as it was inserted in the first place, so that it cannot be said that the insertion resulted in “attaching” the two pieces to each other, as recited in Claim 13. (Indeed, the Examiner’s suggestion that “inherently a large enough male connector would have to be snapped into place” essentially concedes that the *Synthes* document does not contain the required clear teaching of a snapping engagement.) Finally, it is noted that the use of the screw and L-plate suggested in the Office Action, is totally foreign to the manner of use for which such objects are actually intended. Absent some suggestion somewhere in the prior art to depart from the ordinary purpose and manner of use of those objects, it is not understood how one of merely ordinary skill could regard such use as obvious.

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<sup>3</sup> If this is not correct, the Examiner is respectfully requested in his next paper, if he repeats this rejection, to make clear the structures being relied upon. Such rejection, of course, must be non-final.

For these reasons, it is believed that Claim 13 also is plainly allowable over *Synthes*.

Independent Claim 33 is directed to a surgical kit comprising a first surgical implant having a first connector element, and a second surgical implant having a second connector element. According to Claim 33, the first and second connector elements being adapted to engage each other in such manner as to secure themselves together.

From the discussion of *Prescott '157* given above, it is believed clear that that patent does not provide the required clear teaching of the structure recited that would be required to make out a proper rejection. Even if Fig. 6 shows two disks one of which has a stud and the other a hole, there is no actual disclosure that the stud is to be received in the hole, nor that the dimensions of the two actually would permit such insertion. Still less is any disclosure present that would teach or suggest that such insertion, even assuming it to be possible, would result in the two disks being "secured together", as recited in Claim 33. For all that can be determined from the reference, the stud may fit loosely into the hole (assuming, again, insertion were actually suggested) so that no "securing" has been achieved. For all these reasons, Claim 33 also is believed to be allowable over *Prescott '157*.

A review of the other art of record, including *Prescott '280*, has failed to reveal anything which, in Applicant's opinion, would remedy the deficiencies of the art discussed above, as references against the independent claims herein. Those claims are therefore believed patentable over the art of record.

The other claims under consideration in this application are each dependent from one or another of the independent claims discussed above and are therefore believed patentable for the same reasons. Since each dependent claim is also deemed to define an additional aspect of the invention, however, the individual consideration or reconsideration, as the case may be, of the patentability of each on its own merits is respectfully requested.

Moreover, since generic Claims 1 and 2 are believed to be allowable, rejoinder and passage to issue of the other claims withdrawn from consideration and encompassed within the genus defined by either of Claims 1 and 2, is also respectfully requested.

Applicant respectfully requests favorable consideration and early passage to issue of the present divisional application.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

  
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VERSION MARKED TO SHOW CHANGES TO SPECIFICATION

Please rewrite the paragraph at page 2, lines 6-14, as follows:

It would be advantageous to have such implants that can easily and reliably be secured to each other. It would also be desirable to facilitate the surgeon's task by providing kits of pre-assembled combinations of augments with the structures that will secure them in place. In addition, the possibilities for creative new techniques in cosmetic surgery are far from being exhausted [but] by the present conventional techniques and procedures.

Please rewrite the paragraph at page 17, lines 1-8, as follows:

These female connector elements in this embodiment, as shown in greater detail in Figs. 2 and 3, each includes four elements, which together have a shape that can be thought of as a segment or band of a spherical shell, divided into four equal sections by four notches. It will be noted that the top, or notched side, of the female connector element (referring to the orientation in Figs. 2 and 3) is narrower than is the lower side.

Please rewrite the paragraph at page 26, lines 5-9, as follows:

First, any of the augments disclosed as being slide-mountable, may have a groove that is shaped to receive the plain end of a strut, or that is shaped to receive the end having female connector elements, or that is shaped to be able to receive either end of the strut.